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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,011	02/17/2000	John Cooper Cox	017227/0155	6856

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/506,011	COX ET AL.	
	Examiner	Art Unit	
	EMILY LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/12/2007+11/13/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,12-17 and 53-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 12-17 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2007 has been entered.

Status of Claims

2. Claims 2, 4-11 and 18-52 are cancelled. Claims 54-55 are added. Claims 1, 3, 12-17 and 53-55 are pending and under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcon et al.[1]

The claims are directed to a composition comprising a negatively charged organic complex that is electrostaticially associated with a positively charged antigen,

wherein the organic complex is modified to increase the degree of its negative charge and wherein the organic complex comprises saponin and sterol, and that the composition generates a CTL response when administered to a mammal.

Garcon et al. teaches a composition comprising a negatively charged organic complex and a positively charged antigen. The organic complex of Garcon et al., SUV, comprises saponin and sterol. The antigen that Garcon et al. teaches is HSV glycoprotein D (gD). HSV glycoprotein D is positively charged protein, which inherently comprise a peptide region. Additionally, the composition of Garcon et al. also induces a cytotoxic T-lymphocyte response when administered to a mammal. [Pages 10-12, in particular.]

While the organic complex of Garcon et al. has been modified to be negatively charged with the addition of MPL, it should be noted that Garcon et al. recognizes that the addition of charges, negative, to stabilize the organic complex. [Page 2, lines 14-15, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to vary the negative charge of the organic complex. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to optimize the stability of the organic complex. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal range is routinely practiced in the art.

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[1] Garcon et al. WO 96/33739, published

It is recognized that Garcon et al. does not explicitly state that the organic complex and the antigen are electrostaticially associated, as set forth in the claim. However, it is noted that Applicant defines "electrostaticially associated" as a reference to the organic carrier and the antigen being linked, bound or otherwise associated by means which includes electrostatic interaction. [Paragraph bridging pages 9-10 of the specification.] In the instant, Garcon et al. states that the antigen is entrapped with the organic complex. The entrapment or encapsulation of the antigen and organic complex allows the two components to associate with one another. Thus, the composition of Garcon et al. does comprise an antigen and an organic complex that are "otherwise associated" to one another. Additionally, according to Stedman's Medical dictionary, bound is defined as limited, circumscribed; enclosed. Since encapsulation involves enclosure of the antigen within the organic complex, the composition of Garcon et al. does comprise an antigen and an organic complex that are bound to one another. Thus, in view of the insight provided by the specification and the broadest and reasonable interpretation for the term "bound", Garcon et al. does teach a composition comprising an antigen and an organic complex that are "electrostaticially associated" with one another. Furthermore, following the logic of generally chemistry, it logically follows that the addition of positively charged antigens to a negatively charged organic complex would necessary result in an electrostatic association between the two molecules. Applicant is reminded that the "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer."

Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." See MPEP § 2112.

5. Claims 1, 3, 12-17 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcon et al.[2] in vie of McFarlan et al.[3]

The claims are directed to a composition comprising a negatively charged organic complex that is electrostaticially associated with a positively charged antigen, wherein the organic complex is modified to increase the degree of its negative charge and wherein the organic complex comprises saponin and sterol, wherein the positively charged antigen is also modified to increase the degree of its positive charge, and that the composition generates a CTL response when administered to a mammal. The claims later limit the antigen to i) comprise a peptide region, or ii) a protein. The claims require the organic complex to further comprise a phospholipid, which is later limited lipid A or a phosphatidyl glycerol, which is a phosphoglyceride; wherein lipid A is either diphosphoryl lipid A or monophosphoryl lipid A. The claims additionally require the complex to induce a cytotoxic T-lymphocyte response when administered to a mammal.

As mentioned above, Garcon et al. teaches a composition comprising a negatively charged organic complex and a positively charged antigen. The organic complex of Garcon et al., SUV, comprises saponin and sterol. The organic complex of Garcon et al. also comprises a phospholipid. The phospholipids that Garcon et al.

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[2] Garcon et al. WO 96/33739, published

teaches include phosphatidyl choline, which is a phosphoglyceride, and monophosphoryl lipid A. The antigen that Garcon et al. teaches is HSV glycoprotein D (gD). HSV glycoprotein D is positively charged protein, which inherently comprise a peptide region. Additionally, the composition of Garcon et al. also induces a cytotoxic T-lymphocyte response when administered to a mammal. [Pages 10-12, in particular.]

While the organic complex of Garcon et al. has been modified to be negatively charged with the addition of MPL, it should be noted that Garcon et al. recognizes that the addition of charges, negative, to stabilize the organic complex. [Page 2, lines 14-15, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to vary the negative charge of the organic complex. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to optimize the stability of the organic complex. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal range is routinely practiced in the art.

Additionally, it is not readily apparent if in addition to suggesting increasing the negative charge of the organic complex had Garcon et al. also discussed increasing the positive charge of the antigen. However, at the time the invention was made, McFarlan et al. notes that it is difficult to formulate vaccines with proteins or polypeptides using organic complex because of difficulty in efficiently incorporating such proteins or polypeptides in immunostimulating complex matrixes. [Pages 3-4, in particular.] To

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[3] McFarlan et al. WO 98/36772, published August 27, 1998.

circumvent this problem, McFarlan et al. teaches another method of associating antigen with organic complex. The method of McFarlan et al. includes increasing the positive charge of peptides. Specifically, McFarlan et al. teaches adding polyhistidine, which is positively charged, to the peptides. [Lines 5-10, page 5, in particular.] McFarlan et al. also notes that the association between the antigen and the organic complex is important for optimal immune response, including CTL response.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to enhance the association between the positively charged antigen and negatively charged organic complex of Garcon et al. by varying the degree of positive charge on the antigen. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to optimize the immune response induced by the antigen and organic complex. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal range is routinely practiced in the art.

As discussed above, it is recognized that Garcon et al. does not explicitly state that the organic complex and the antigen are electrostaticially associated, as set forth in the claim. However, it is noted that Applicant defines "electrostaticially associated" as a reference to the organic carrier and the antigen being linked, bound or otherwise associated by means which includes electrostatic interaction. [Paragraph bridging pages 9-10 of the specification.] In the instant, Garcon et al. states that the antigen is entrapped with the organic complex. The entrapment or encapsulation of the antigen

and organic complex allows the two components to associate with one another. Thus, the composition of Garcon et al. does comprise an antigen and an organic complex that are "otherwise associated" to one another. Additionally, according to Stedman's Medical dictionary, bound is defined as limited, circumscribed; enclosed. Since encapsulation involves enclosure of the antigen within the organic complex, the composition of Garcon et al. does comprise an antigen and an organic complex that are bound to one another. Thus, in view of the insight provided by the specification and the broadest and reasonable interpretation for the term "bound", Garcon et al. does teach a composition comprising an antigen and an organic complex that are "electrostaticially associated" with one another. Furthermore, following the logic of generally chemistry, it logically follows that the addition of positively charged antigens to a negatively charged organic complex would necessary result in an electrostatic association between the two molecules. Applicant is reminded that the "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." See MPEP § 2112.

Double Patenting

6. In response to the rejection, Applicant submits that Applicant intend to continue deference any argument or "corrective" action concerning the rejection until allowable subject matter is arrived upon.

Applicant's submission has been considered. However, until the rejection is properly addressed, the rejection is maintained. Below is the double patenting, provisional, rejection.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 53-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50 of copending Application No. 10/622470. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed invention is directed to a composition comprising a negatively charged organic complex that is electrostaticially associated with a positively charged antigen, wherein the organic complex is modified to increase the degree of its negative charge and wherein the organic complex comprises saponin and sterol.

The invention claimed in the copending patent application is also directed to a composition comprising a negatively charged organic complex that is electrostaticially associated with a antigen, wherein the organic complex is modified to increase the degree of its negative charge, wherein the organic complex comprises saponin and sterol, and wherein the antigen is on or more polypeptides from a region of Hepatitis C virus selected from a group consisting of Core, E1, E2, NS3, NS4a, NS4b, NS5a and NS5b.

The difference between the two inventions is: the antigen of the copending patent application is limited to Hepatitis C virus selected from a group consisting of Core, E1, E2, NS3, NS4a, NS4b, NS5a and NS5b. Additionally, the specification of the copending patent application provides that the listed antigens are positively charged. In the instant case, the positively charged antigens recited in the claims of the copending patent application is encompassed by the genus of positively charged antigens recited in the instantly claimed invention. The species recited in the copending patent application has anticipated the genus of positively charged antigens. This is an anticipatory type double patenting rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel

recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Patent Examiner, Art Unit 1648

/E. L./